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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,819	08/08/2002	John Hughes	A0000005/1-01-MG	5592

7590 03/28/2005

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EXAMINER	
SHARAREH, SHAHNAM J	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,819	HUGHES ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on November 5, 2004 has been entered. Claims 1-17 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the claim amendments. Applicant's arguments regarding the pending rejections are addressed below.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-4, 9 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling specific compounds of claims 5-8 does not reasonably provide enablement for the entire scope of the phrases "NK1 receptor antagonists" or "GABA analogs." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

4. Applicant first asserts that specification teaches various NK1 receptor antagonists or GABA analogs and that such teachings are sufficient to meet the requirement of 112 1st paragraph. (*see* Remarks at page 5-6). For example, Applicant states that specification teaches gabapentin as gamma- amino butyric acid (GABA) structural analog and that the skilled person would understand what compounds are

encompassed by the term "GABA analog" because such compounds should possess the same properties as gabapentin and pregablin. (*see Id.*)

In response Examiner states that Applicant's arguments are not commensurate with the scope of the claims because claims 1-4 are not directed to gabapentin or pregabtin or any specific NK 1 receptor antagonists. Moreover, the description provided in the specification for GABA analogs and NK1 receptor antagonists are not exclusive, rather inclusive of any agent that can respectively provide a function similar to Gapapentin or NK1 antagonists known in the art.

For example, GABA analogs as described in the specification at the pages 1 and 7 encompass any cyclic amino groups that can provide the same function as gabapentin. Such description does not limit the scope of the claims to only GABA analogs. On the contrary, Examiner viewed such description as a teaching to establish that "Gabapentin-like molecules, are capable of providing a function similar to GABA." There is no unifying structural similarity established in the art to show that Gabapentin represents the entire scope of the compounds encompassed by the term "GABA analogs." Similar argument holds true for the limitation "NK1 antagonists." Thus, Applicant has not provided adequate teaching to enable the entire scope of such molecules claimed as GABA analogs or NK1 receptor antagonists.

5. Applicant then argues that one of ordinary skill in the art would understand which compounds are capable of providing same properties and subsequently is able to ascertain the scope of the term "GABA analog," and "NK1 receptor antagonists."

In response, Examiners states that placing a functionality at the point of novelty does not meet the standards set forth under 35 USC 112, 1st paragraph. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty." Functional language at the point of novelty, as herein employed by Applicants, is also admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate."

Generally, claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Further, as it has repeatedly been stressed by the Courts, an assay for determining whether a given compound possesses certain desired characteristics and identifies some broad categories of compound that might work, these descriptions, without more precise guidelines, amount to little more that "a starting point, a direction for further research." See *Genetech v. Novo Nordisk A/S,* 108 F.3d 1361,1366,(Fed. Cir.), also *Enzo Biochem, Inc. V. Calgene*, Inc, 1888 F.3d 1362, 1374 (Fed. Cir. 1999).

In the instant case, specification attempts to provide a method for treating chronic pain by providing a synergistic combination of any GABA analog and any NK1 receptor antagonists without enabling the entire scope of the claims. Applicant argues that one of ordinary skill in the art would have known which analogs of GABA or NK1 antagonists would provide pain control.

Such line of arguments places a function at the point of novelty. Essentially, Applicant claims a method of treatment comprising administering compounds that possess certain desired characteristic. Claims as constructed provide no guidance as which GABA analogs are envisioned or are able to provide a synergistic effect for treatment of chronic pain when employed in combination with NK1 receptor antagonist. As has been reasoned by Courts, such attempts do not satisfy the statutory requirement set forth under 112 1st paragraph. Simply stated, the presented claims are an invitation to experiment, not reciting a specific therapeutic regimen useful for practicing the instant invention. Thus, practicing the entire scope of the instant claims require undue experimentation.

Claim Rejections - 35 USC § 103

6. Claims 1-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Horwell in view of Byrans.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

7. Applicant appears to argue that since there is neither teaching nor suggestion in either reference to combine the teachings of the cited references, the claims are clearly

patentable over the combination, even if the combination were to be applied in opposition to applicable law. (see Remarks at page 7, 1st para.).

In response to Applicant's conclusionary statements Examiner sees no reasons to forgo an applicable case law on point, merely because the applied prior art fail to explicitly suggest a combination of their own teachings with the other cited reference. Rather, such suggestion or motivation is ascertained in view of the understanding of one of ordinary skill in the art when presented with the cited references at the time of invention.[1] Applicant has not provided any legal basis as to why the case law on point is not applicable. Thus, Applicant has not met the burden of non-obviousness.

Further, Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the cited references provide ample knowledge in the art that both gabapentin and NK1 antagonists are used for treating chronic pain. (see Bryans, the entire abstract; see Horwell, col 8, lines 12-14 and example 66). Thus, one of ordinary skill in the art would have had reasonable expectation of success to treat chronic pain by combining both such compounds. Expectation to observe additive effects by

[1] See the factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a). The court recognized "Resolving the level of ordinary skill in the pertinent art" as one of such factors.

combining drugs with similar utility is not only readily practiced in the clinical settings but also articulated by the court in *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

8. Applicant also appears to argue that the instantly recited "synergistic effects" of the combination has not been described in the cited references. However, Applicant has failed to establish unexpected results commensurate with the scope of the pending claims. In fact, the instant Figures 2(b) and 2(c) set forth that there is a general expectation in the art to observe improved chronic pain control by adding gabapentin and a NK1 antagonist. Applicant has failed to establish any unexpected results directed to the claimed synergy. In fact the presented results are directed to specific dosing, specific compounds and specific regimens. The presented claims are not commensurate with the scope of such data. Thus, Applicant's arguments are not found persuasive and the rejection stands.

Conclusion

9. **No claims are allowed. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENIVASAN PADMANABHAN
SUPERVISORY PATENT EXAMINER